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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,072	02/27/2002	Laurie DeLeve	13761-7065	1401

7590 06/03/2003

Jennifer M. Phelps
McCutchen, Doyle, Brown & Enersen, LLP
18th Floor
Three Embarcadero Center
San Francisco, CA 94111

EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/03/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,072

Applicant(s)

DELEVE, LAURIE

Examiner

Mojdeh Bahar

Art Unit

1617

– **Th MAILING DATE of this communication appears n the cover sheet with the correspondence address –**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 16 and 18, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant's amendments and response to the office action of August 9, 2002, submitted December 16 and 18, 2002 is acknowledged. Applicant's amendments are persuasive to remove the objection and rejections under 35 USC 112 in the previous office action.

Applicant's remarks concerning the rejection of claim 10 under 35 USC 102 is persuasive and the rejection has been modified in that claims 1-5 are now included along with claim 10 in this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 9, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Periostat (doxycycline capsules).

Periostat (doxycycline capsules) teaches twice a day administration of doxycycline to adult patients, see Clinical Study page 945 in particular.

Claims 1-5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by McKearn et al. (WO 00/38717).

McKearn et al. (WO 00/38717) teaches a method comprising employing matrix metalloproteinase inhibitor in combination with radiation therapy, see abstract in particular. McKearn et al. (WO 00/38717) further teaches the following MMPs specifically: Marimastat, Metastat, Bay-12-9566 and D-2163, see page 71 for example.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9, 11-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Periostat (doxycycline capsules).

Periostat (doxycycline capsules) teaches the administration of 20 mg twice a day of doxycycline to adult patients, see Clinical Study page 945 in particular.

Periostat (doxycycline capsules) does not teach the administration of 15 mg twice daily of doxycycline to adult patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer 15 mg twice daily of doxycycline to adult patient.

One of ordinary skill in the art would have been motivated to administer 15 mg twice daily of doxycycline to a patient because optimization of amounts is within the skill of the artisan and is therefore obvious.

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Claims 4, 7-10, 14-15 and 17 are rejected under 35 USC 103 as being unpatentable over McKearn et al. (WO 00/38717) and Watanabe et al. (USPN 6,150,394).

McKearn et al. (WO 00/38717) teaches a method comprising employing matrix metalloproteinase inhibitor in combination with radiation therapy, see abstract in particular. McKearn et al. (WO 00/38717) further teaches the following MMPs specifically: Marimastat, Metastat, Bay-12-9566 and D-2163, see page 71 for example.

Watanabe et al. (USPN 6,150,394) teaches a method comprising administering 0.01 mg/kg/day to 100 mg/kg/day of compositions comprising MMPs of formula I (which encompass 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid), see col. 19, lines 13-35. Watanabe also teaches that its compositions can be administered parenterally, see col. 19, lines 37-47.

McKearn et al. (WO 00/38717) and Watanabe et al. (USPN 6,150,394), taken together do not specifically teach the 100-200 mg/hour administration of 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid in their methods of administering MMPs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer 100-200 mg/hour of 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid to the patient.

One of ordinary skill in the art would have been motivated to administer 100-200 mg/hour of 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid to a patient because optimization of amounts is within the skill of the artisan and is therefore obvious.

Response to Arguments

Applicant's arguments filed December 16, 2002 have been fully considered but they are not persuasive. Applicant argues that since the disclosure of Periostat is not enabling, it does not

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anticipate claims 1-5, 9 and 11-12. Note that the instant claims do not designate a particular host. The method herein simply requires the administration of a metalloproteinase inhibitor. The host need not have a particular condition, disease or disorder. Given that all hosts need a prophylactic measure against liver disease in general and Sinusoidal Obstruction Syndrome specifically so long as an MMP has been administered in the regimen claimed herein the claimed limitations are met. Note that so long as the same amount of the same substance is administered to a host, the method claimed herein is anticipated.

Applicant's arguments concerning the obviousness rejection under 35 USC 103 have been fully considered but they are not persuasive. As discussed in response to the anticipation rejection herein above, the instant method does not designate a particular host.

Applicant's arguments with respect to the rejection(s) of claim(s) 10 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection now includes claims 1-5 in addition to claim 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

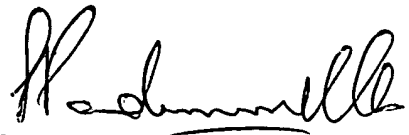
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Mojdeh Bahar
Patent Examiner
May 29, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

6/1/03